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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,661	11/28/2000	Derek O'Hagan	1413.101	7716

7590 05/14/2003

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EXAMINER

STUCKER, JEFFREY J

ART UNIT	PAPER NUMBER
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1648

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DATE MAILED: 05/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

Applicant(s)

Examiner

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on 4/28/03
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-3, 5-7, 11, 14-19, 21, & 22 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-3, 5-7, 11, 14-19, 21, & 22 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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Art Unit: 1648

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This Office Action is in response to the amendment filed 4/28/03. Claims 1-3, 5-7, 11, 14-19, 21, and 22 are pending and are under final rejection.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The objection to claim 22 for the misspelling of "microsphere" is withdrawn in view of the amendment to the claim.

The rejection of claims 1-3, 5-7, 11, 14-19, 21, and 22 rejected under 35 U.S.C. § 103(a) as obvious over Callegaro et al. (EP 0 517 565 A3) in view of both Partidos et al. (Immunology 1996) and Koichiro (JPO 05163161, IDS ref. AO-1).

Applicant argues that Callegaro et al. fails to teach the use of an influenza antigen and that hyaluronic acid microspheres could be used for vaccines and that complicated mechanisms are involved in an immune response and that there is no recognition in Callegaro et al. that vaccine antigens could be delivered using hyaluronic acid composition. Applicant further argues that Partidos et al. pertains to intranasal administration of a measles epitope in combination with LTK63 and that neither the epitope or LTK63 is in any way associated with a delivery particle such as a hyaluronic

acid microsphere. Applicant's arguments concerning Koichiro abstract are that the reference is silent regarding the form of the hyaluronic acid used. Applicant further argues that the claimed invention provides a significantly greater immune response than the use of the antigen or the antigen and LTK363 alone and that the references do not suggest this, only bits and pieces of this with no "glue" to hold them together. Applicant references *Symbol Technologies, Inc.* and *In re Fritch* and *In re Fine*. Applicant further argues improper hindsight and a lack of suggestion or motivation to combine the references.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). This is why the references are combined under 35 U.S.C. § 103(a).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the

claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, applicant argues that the claimed invention provides a significantly greater immune response than the use of the antigen or the antigen and LTK363 alone. This is not in contention and would be expected. The artisan recognizes that to be a useful adjuvant, a composition must have a) the ability to protect and steadily release the immunogen while protecting it from catabolism and b) induce an immune response. This concept is notoriously known in the art as evidenced by Harlow and Lane (*Antibodies: A Laboratory Manual*, "Harlow"), a standard immunology reference book and is the "glue" to bring the references together. The use of oils or particles

such as aluminum hydroxide precipitates have been used to fulfil the first criteria. This teaches that the antigen can be absorbed on the surface for continuous presentation to the immune system. Callegaro et al. teach that hyaluronic acid is a known and widely used polymeric carrier for release systems for pharmacologically active molecules by attaching proteins to the surface of hyaluronic acid ester microspheres for steady release into the body. This meets the art recognized criteria of "a)", above. The second component, a substance that will stimulate the immune system is met by the teachings of Partidos et al. teach LTK63 as an effective mucosal adjuvant.

Harlow et al. set forth broad guidelines, though not exhaustive, that the artisan would recognize as necessary for developing an adjuvant as a framework to guide formulation of an adjuvant. Given the knowledge in the art concerning adjuvant requirements as evidenced by Harlow et al. and the compositions known in the art as set forth in the art of record for the reasons explained above, the instant invention is obvious over Callegaro et al. in view of both Partidos et al. and Koichiro.

No claims are allowed.

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THIS ACTION IS MADE FINAL. See M.P.E.P. § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

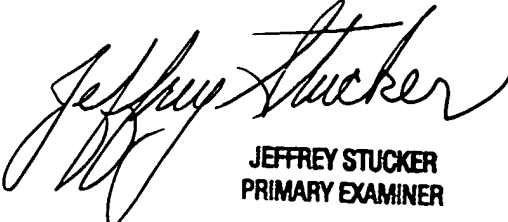
The Group 1600 Fax numbers are: (703) 308-4242 and (703) 305-3014.

Unofficial communications may be faxed to: (703) 308-4426.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (703) 308-4237. The examiner can normally be reached Monday to Thursday from 7:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


JEFFREY STUCKER
PRIMARY EXAMINER